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C-A OPERATIONS PROCEDURES MANUAL

13.3.1 Graded Approach for Quality Requirements

Text Pages 2 through 5

Attachments

Hand Processed Changes

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Collider-Accelerator Department Chairman Date

D. Passarello

13.3.1 Graded Approach for Quality Requirements

1. Purpose

The purpose of this document is to provide guidance when applying the graded approach to the selection of Quality Assurance Classifications for C-AD systems, subsystems, and assemblies. This document supplements the requirements of the Graded Approach for Quality Requirements Subject Area.

A graded approach to quality is used to place the most emphasis on and allocate proper resources to those items and/or processes that may have the greatest effect upon personnel, environment, safety, security, health, cost, data, equipment, performance, and schedule.

The graded approach is a process for determining that the appropriate level of analysis, management controls, documentation, and necessary actions to comply with requirements are commensurate with an item's or activity's potential to

- Create an environmental, safety, security, health or radiological hazard;
- Incur a monetary loss due to damage, or to repair/rework/scrap costs;
- Reduce the availability of a facility or equipment;
- Adversely affect the program objective or degrade data quality;
- Unfavorably impact the public's or regulator’s perception of the BNL/DOE mission.

In addition to providing guidance in the application of the graded approach, this document contains the list of C-AD Safety Software, Attachment 2, C-AD A1 Systems, Attachment 3, and C-AD Continuous–Use Checklist, Attachment 4.

2. Responsibilities

C-A staff shall apply the requirements of this document during the development and design stages of, and procurement for, a project, program, experiment, study, process, or system.

3. Prerequisites

None

4. Precautions

None

5. Procedure

5.1 Using the criteria in Attachment 5, QA Graded Approach Classification Matrix, consider the following when reviewing for the application of the graded approach:

- The graded approach (i.e. Quality Classification) should be based on the programmatic and/or environmental, safety, security & health (ESS&H) impact.

  The classification assigned to a subsystem or process may be more significant than the classification assigned to the overall system, process or experiment (i.e., System = A-3 and Subsystem = A-2). Similarly, the classification assigned to the lower levels may be less significant than the higher level, (i.e., Assembly = A- 2 and Subassembly = A-3).

- Although an attempt has been made to quantify adverse impacts, engineering judgment and adequate margins of safety must be considered when selecting a classification. The classification selected should be based on the most severe effect of the failure.

- Costs should consider all expenses, e.g., replacement cost, cost of labor, downtime (due to real or perceived issues), injuries, investigation efforts, cleaning (including decontamination), renovating, replacing, or rehabilitating structures, equipment, or property.

  Intangible costs of equipment failure must also be considered. For example, the intangible cost for shutting down the accelerator complex for one month in the event of equipment failure is significant. It is understood that intangible costs are difficult if not impossible to predict.

5.2 Attachment 1, Engineering Activity Guide by Classification Category, describes recommended activities for specific classifications. The responsible individual determines which activities are applicable to their particular design/procurement.

5.3 When an engineering drawing or specification is prepared, the responsible individual will determine which QA Classification is applicable to the item(s) defined by the drawing or specification. If a drawing or specification defines an assembly, each item within the assembly shall be assigned a QA classification.

5.3.1 When an assembly or subsystem is to be procured as a deliverable end item, only the end item needs a QA Category assigned.

5.3.2 Items requisitioned from BNL general stock (S&M) are automatically classified as A4. If it is determined that the category A4 is inadequate, then additional testing and/or inspection of the critical aspects of the general stock item prior to its use must be specified.

5.4 If an items does not have a QA classification designation, the responsible individual with the assistance of the C-AD QA Office, shall determine the proper QA classification. When appropriate, division management shall concur with QA classification assignment.

5.5 Appropriate consideration shall be given to an items critical aspects when determining the QA classification designation and selecting the Seller QA Requirements for "off-the-shelf" items. "Off-the-shelf" items are manufactured by a supplier for inventory, rather than a specific order, or are items supplied by an independent distributor. Some catalog items are "made-to-order" and are not considered to be off-the-shelf items.

5.6 In order to further assist in properly classifying all systems, subsystems, assemblies, subassemblies and components, the following considerations should be used as guides:

5.6.1 Safety - A system, subsystem, assembly, or component which will be relied upon to prevent or mitigate the consequences of a major facility accident or significant radiological incident within the facility, including experimental areas, should be classified as critical (A1).

Engineered safety systems, subsystems, assemblies, or components designed to protect personnel from direct radiation, electrical, mechanical, chemical or cryogenic hazards (such as safety systems, ionizing radiation shielding), should generally be classified as critical (A1) in lieu of classifying the hazardous equipment itself.

For example, if a capacitor bank for a power supply system poses a significant electrical hazard to personnel, rather than classifying the capacitor bank as A1 from a safety viewpoint, the gate interlock system preventing access to the capacitor bank during hazardous conditions should be classified A1.

From a safety viewpoint, the incorporation of component redundancy, independence or diverse design, or objective evidence showing that failures are "remote" or "extremely remote", or showing that failures would result in a non-hazardous condition, could provide an acceptable basis for lowering the classification level.

5.6.2 Quantity, Cost or Schedule - When the cost of an item or quantity of items is high (i.e. exceeds $10,000 for Category A4), or the lead time to purchase or produce the item or quantity of items is long, it may be necessary to upgrade the QA Category to protect against a potentially significant adverse cost or schedule impact.

For example, a single electronic component of a particular type may potentially have a minor impact upon system availability and reliability, but when a large quantity of that component is used in a system the potential impact upon availability and reliability may be major.

6. Documentation

The QA classification designation shall be specified on procurement documentation, drawings and/or specification cover sheets.

7. References

7.1 SBMS, Graded Approach for Quality Requirements.

8. Attachments

8.1 Recommended Engineering Activity Guide by Classification Category

8.2 C-AD Safety Software

8.3 C-AD A1 Systems

8.4 C-AD Continuous-Use Checklists

8.5 QA Graded Approach Classification Matrix

Recommended Engineering Activity Guide by Classification Category

Attachment 1

ENGINEERING ACTIVITIES	Category			
	A4	A3	A2	A1[1]
Training				
• Use of qualified personnel. • Training must be identified, completed, recorded, maintained, and reviewed before work commences. OPM 1.12, Training and Qualification Plan Training and Qualifications Subject Area			X	X
Design				
• Plan design effort (develop milestones) & define design criteria. • Prepare/distribute drawings, specification, and other design documentation that are considered necessary to define the design parameter of the item/process. This includes determining appropriate codes, standards, and practices. • Perform design reviews (as required). OPM 13.6.1, Preparation & Issuance of Engineering Drawings/Specifications OPM 13.6.2, Configuration Management OPM 13.6.3, Programmable Device/Assembly Documentation Engineering Design Subject Area		X	X	X
Procurement				
• Specify QA requirements in the purchasing documents. (When feasible, specify the requirements of BNL-QA-101). OPM 13.7.1, C-A and SMD Procurement Guidelines Purchase Requisition Review for Quality-related Requirements Subject Area		X	X	X
• Evaluate the capability of suppliers of critical, costly, or complex items. • Evaluate alternate proposals/exceptions from suppliers. OPM 13.7.1, C-A and SMD Procurement Guidelines Supplier Pre-Award Evaluation Subject Area			X	X
Work Process				
• Prepare procedures/work permits considered necessary for conducting the activity or experiment. • Prepare/review operating/maintenance procedures for check-out, start-up, and operations for facilities/equipment • Prepare procedures/work permits for complex items. OPM 2.28, C-A Procedure for Work Planning and Control for Operations OPM 2.29, C-A Procedure for Enhanced Work Planning for Experimenters Work Planning and Control Subject Area, Internal Controlled Documents Subject Area			X	X
• Identify, protect, and control material that has been identified as age-sensitive (Items with limited calendar/operating life) and items subject to environmental deterioration. OPM 13.5.1 Process and Material Management http://www.cadops.bnl.gov/AGS/Accel/SND/OPM/Ch13/13-08-01.PDF Materials Requiring Special Handling (Including Age Sensitive Material) Subject Area	X	X	X	X

ENGINEERING ACTIVITIES	Category			
	A4	A3	A2	A1[1]
• Identify and document special requirements for handling, storage and transport. • Assure special processes are performed & verified, by technically competent personnel, in accordance with written procedures. OPM 13.5.1 Process and Material Management Materials Requiring Special Handling (Including Age Sensitive Material) Subject Area			X	X
Inspection and Acceptance Testing				
• Conduct source, receiving, in process, and final inspection/testing of specified items, services, and processes using established acceptance and performance criteria. OPM 13.8.1, Inspection & Acceptance Inspections and Acceptance Subject Area		X	X	X
Control of Nonconforming Items				
• Identify, control, and correct items, services, and processes that do not meet established requirements. • Inform Division of Contracts & Procurement of defective materials which are received. OPM 13.3.2, Identifying and Reporting Nonconformance Nonconformances, Identifying and Reporting Subject Area		X	X	X
• Indicate inspect/test status on the item or on documentation traceable to the item. • Provide traceability to the items/lots inspected OPM 13.8.1, Inspection & Acceptance			X	X
Corrective and Preventive Action				
• Determine the cause of nonconformances and develop remedies to preclude the recurrence. Event/Issues Management Subject Area			X	X
Control of Measuring and Test Equipment				
• Establish calibration procedures and frequency for equipment and devices considered necessary to meet the project's objectives and safe conduct of operations/experiments • Identify equipment requiring calibration, establish calibration frequency and show calibration status on equipment OPM 13.8.2, Calibration Calibration Subject Area		X	X	X
Records				
• Identify records documenting actions taken during an experiment/operation that have affected execution, milestones, or ESH&Q issues. • Identify and control items that are considered necessary for meeting objectives and for safely conducting the activity or experiment to ensure their proper use. • Prepare & maintain records of actions affecting quality[2]. OPM 13.4.1, Records Management OPM 13.4.2, Records Index Records Management Subject Area Work Planning and Control Subject Area		X	X	X

Table 2

[1]Activities listed for Category A1 systems, subsystems, and assemblies are mandatory. For all other Categories, listed activities should be considered by the CE/CS

[2]Quality Assurance Records include Inspection & Test Results (Internal & Vendor Items); Calibration Records; Material Certifications; Waivers/Deviations; and Nonconformance Reports.

Safety Software

Attachment 2

Brief description of the software's function	Point of Contact:		ESH&Q Risk Level (A1, A2, A3, A4), if known
	Name	Ext.	
MicroShield - shielding calculations	D. Passarello	7277	Not Classified, COTS [1]
MCNPX - calculations for shielding, beam loss energy deposition, etc…	D. Passarello	7277	Not Classified, (code is maintained at LANL)
Radioactive Waste Calculation - Calculations for isotropic content of radiactive waste	E. Lessard	4250	A2
Particle Accelerator Safety System (PASS) - controls access, detects radiation levels outside shielded areas & detects oxygen deficiency hazard (ODH) conditions	Passarello	7277	A1
SKM Systems Analysis, Inc. Software is Power Tools, with the modules Dapper, Captor, Arc Flash, and Equipment Evaluation The program calculates: short circuit currents, over current protection, arc flash, and equipment evaluation has to its application.	Nehring	5275	Not Classified, COTS [1]

[1] COTS – Commercial Off The Shelf

C-AD A1 Systems

Attachment 3

The following systems preventive and/or mitigative functions are a major contributor to defense-in-depth and/or worker safety as determined in the C-AD SAD and ASE.

1. C-AD Access Control System for Tandem Van De Graaff (deuterons only), SEB, AGS, LINAC and Booster: QA 1 classification assigned to the engineering drawings which define the installation of the system.

2. C-AD Particle Accelerator Security System (PASS) for g-2, ATR, RHIC and NSRL: QA 1 classification assigned to the engineering drawings and state tables which define the installation and operation of the system. In addition, all PASS software has been classified as QA 1

3. C-AD Ionizing Radiation Shielding: QA 1 classification assigned to the engineering drawings which define the ionizing radiation shielding, e.g. location of blocks, thickness of berm.

4. Flammable Gas Monitor System: QA 1 classification assigned to the engineering drawings and state tables which define the installation and operation of the system.

5. Fire Detection System for Accelerator Enclosure: BNL Plant Engineering is responsible for the installation, maintenance and testing of this system. C-AD ESSHQ Division ensures that required annual testing is performed.

C-AD Continuous-Use Checklists

Attachment 4

As of the issue date of this document no continuous-use checklists are in use within the Collider-Accelerator Department

QA Graded Approach Classification Matrix[1]

Attachment 5

PROBABILITY / CONSEQUENCE OF FAILURE		**FREQUENT** Likely to occur repeatedly in life cycle	**PROBABLE** Likely to occur several times in life cycle	**OCCASIONAL** Likely to occur some time in life cycle	**REMOTE** Unlikely to occur in life cycle but possible	**EXTREMLY REMOTE** Likelihood of occurrence ~ zero	**IMPOSSIBLE** Physically impossible to occur
A1	• hazard can cause a death or serious injury, • off-site evacuation • ≥25 rem to an individual, • >$250,000 or ≥50% of item/material/program cost • ≥3 weeks program downtime or ≥30% of program schedule • severe loss of experimental data or equipment output • have a public impact that closes down an expriment or program or have a critical impact on BNL/DOE mission and program	A1	A1	A1	A1	A1 or A2	A1 or A2
A2	• hazard can cause moderate injuries, • local evacuation, • accident condition > 1 rem or > ERPG-1 at site boundary for mitigated release[2&3] • ≥ 5 rem to an individual (Federal Law Violation) • > $50,000 or ≥10% of item/material/program cost • ≥4 days program downtime or ≥10% of program schedule • major loss of experimental data or equipment output • have a public impact that brings the experiment to the attention of the community and activist groups or have a major impact on BNL/DOE mission and program	A1	A1	A2	A2	A2 or A3	A2 or A3
A3	• hazard can cause minor injuries, • no on-site or off-site evacuation, • ≥ 100 mrem to an individual (ORPS trigger) • ≥ $10K or ≥ 2% of item/material/program cost • ≥2 days program downtime or ≥ 2% of program schedule • minor loss of experimental data or equipment output • have a public impact that is below public perception or have a minor impact on BNL/DOE mission and program	A2	A2	A3	A3	A3 or A4	A3 or A4
A4	• no hazard present • <100 mrem to an individual • < $10,000 or <2% of item/material/program cost • < 2 days program downtime or <2% of program schedule • no loss of experimental data or equipment output • no impact on public perception or BNL/DOE mission and program	A3	A3	A4	A4	A4	A4

[1] The QA classification is based on the potential consequence and the probability of that consequence occurring.

[2] EPA Protective Action Guide (PAG): US EPA, Office of Radiation Programs, Manual of Protective Action Guides and Protective Actions for Nuclear Incidents (400-R92-00l)

[3] Emergency Response Planning Guideline (ERPG) values are intended to provide estimates of concentration ranges where one reasonably might anticipate observing adverse effects as described in the following definitions as a consequence of exposure to the specific substance. See: American Industrial Hygiene Association, *2004 Emergency Response Planning Guidelines (ERPG) Update Set* (Stock number: AEAR04-561).

- The ERPG-l is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hr without experiencing other than mild transient adverse health effects or perceiving a clearly defined, objectionable odor.
- The ERPG-2 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hr without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.
- The ERPG-3 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to I hr without experiencing or developing life-threatening health effects.